



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

Ref: Customs Entry No. ATO-0033981-5/001/002  
Grouper & Red Snapper

WARNING LETTER

FLA-99-59

May 3, 1999

Mr. Carlos Sanchez  
Vice President  
Freskito International, Inc.  
8151 S.W. 62<sup>nd</sup> Avenue  
Miami, Florida 33143-8033

Dear Mr. Sanchez:

The Food and Drug Administration (FDA) attempted to examine 158 cartons (17,565 lbs.) of fresh red snapper and fresh grouper offered for entry into the United States by your firm on April 14, 1999, under the above referenced entry number, and found that the shipment was not available for FDA examination. Title 21, Code of Federal Regulations (21 CFR), Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We requested the U. S. Customs Service (Customs) to order redelivery of this shipment (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

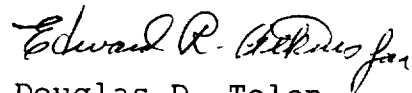
We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation. Your response should include an explanation of each step being taken to prevent the recurrence

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of the violation. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Your written reply should be addressed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in cursive script, appearing to read "Douglas D. Tolen".

Douglas D. Tolen  
Director, Florida District

Enclosure